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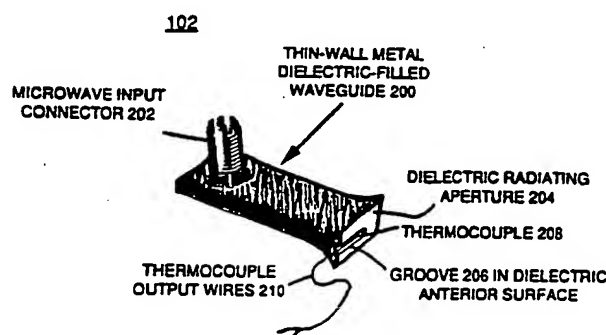
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(54) Title: THERMOSTATICALLY-CONTROLLED MICROWAVE CYCLODESTRUCTION AS A TREATMENT FOR GLAUCOMA



(57) Abstract

A miniaturized microwave applicator comprises a thin-wall metal dielectric-filled waveguide (200) having a thermocouple (208) disposed in a groove (206) in the surface of the dielectric radiating aperture of the waveguide (200). When the aperture is placed in contact with a spot on the outer surface of the sclera overlying the ciliary body to cyclodestruct by heat generated by absorbed microwave energy radiated thereto during a given time, damage due to overheating of the scleral tissue is prevented by the thermocouple (208), which monitors the sclera surface temperature, being used to thermostatically control the microwave energy supplied to the waveguide in a manner that the scleral tissue temperature is maintained substantially constant at a value below that which would cause damage thereto. The desired operation is dependent on the fact that very little of the microwave energy is absorbed by the lower-water-content scleral tissue as it passes therethrough, but is highly absorbed by the underlying high-water-content ciliary-body tissue.

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THERMOSTATICALLY-CONTROLLED MICROWAVE
CYCLODESTRUCTION
AS A TREATMENT FOR GLAUCOMA

5

BACKGROUND

As known in the art, several different cyclodestruction
10 procedures (i.e., procedures for destroying the ciliary body) have
been developed or proposed for treating glaucoma. The clinical
standard cyclodestruction procedure employs cryotherapy. Other
known cyclodestruction procedures include therapeutic
ultrasound and Neodymium:Yag cyclophotocoagulation. However,
15 all of these known cyclodestruction procedures have
demonstrated different negative tissue reactions.

Cryotherapy has been characterized by discomfort and
edema, therapeutic sound by induced scleral changes, and
Neodymium:Yag cyclophotocoagulation has been shown to cause
20 characteristic spot-like conjunctival lesions. Other less specific
morbiditys have included corneal-scleral thinning, hyphema,
cataract, vitritis, retinal detachment, cystoid macula edema, and
hypotony. These potential complications have defined
cyclodestruction procedures as a last treatment for refractory
25 cases.

SUMMARY OF THE INVENTION

The present invention is directed to a microwave
30 cyclodestruction procedure which avoids negative tissue reactions
and minimizes potential complications. The microwaves are
applied to the ciliary body by a novel miniature microwave
applicator placed in contact with a spot on the outer surface of the
sclera. The miniature microwave applicator incorporates a
35 thermocouple on its anterior radiating surface, so that the
thermocouple also contacts the spot on the outer surface of the
sclera. The thermocouple thermostatically controls the output of

the microwave generator energizing the applicator to ensure that the temperature of the scleral tissue never rises to an unsafe level. Because scleral tissue absorbs less microwave energy, while ciliary-body tissue absorbs more microwave energy, most of the applied applied microwave energy penetrates through the sclera to, and is absorbed by, the underlying ciliary body. This raises the temperature of the ciliary body to the point at which some cyclodestruction occurs. This process may be repeated at several separate spots of the sclera to complete the microwave cyclodestruction procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a functional block diagram showing the relationship between a miniature microwave applicator incorporating a thermocouple (which may take the form shown in FIGURE 2) and a thermostatically-controlled microwave generator for energizing the applicator;

FIGURE 2 illustrates the physical form of a preferred embodiment of the miniature microwave applicator incorporating a thermocouple that is used for microwave cyclodestruction;

FIGURE 3 is a first chart useful in explaining the principles of the present invention; and

FIGURE 4 is a second chart useful in explaining the principles of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGURE 1, the microwave output of thermostatically-controlled microwave generator 100 is applied as an input to miniature microwave applicator incorporating a thermocouple 102 (which may take the form shown in FIGURE 2) over a suitable microwave transmission line 104. The thermocouple of applicator 102 generates a control signal having a value which is a function of the temperature at the microwave radiating aperture of applicator 102. This control signal, which is fed back to microwave generator 100 over connection 106 to

thermostatically control microwave generator 100, prevents microwave energy from being forwarded from the output of microwave generator 100 over transmission line 104 to the input of applicator 102 whenever the temperature of the thermocouple rises to a certain preselected temperature.

Referring to FIGURE 2, applicator 102 comprises thin-wall metal dielectric-filled waveguide 200. In practice, waveguide 200 is fabricated from a block of ceramic material that exhibits a high dielectric constant (e.g., 85) that is machined to the proper size and shape. The longitudinal surface of this properly sized and shaped ceramic material is first electrolessly plated with metal and then electroplated with metal to produce the thin metal wall of waveguide 200. More specifically, the length of waveguide 200 is preferably about one inch; the width of waveguide 200 is preferably about 0.2 inch (i.e., 200 mils); and the thickness of waveguide 200 preferably tapers from about 0.1 inch (i.e., 100 mils) at its posterior end, to which microwave input connector 202 is attached, to about 0.15 inch (i.e., 150 mils) at its anterior end, which forms dielectric radiating aperture 204. Thus, the area of dielectric radiating aperture 204 is quite small, being only 0.03 square inch.

As shown in FIGURE 2, the dielectric anterior surface, which is preferably flat, has a groove 206 machined therein in which thermocouple 208 is fixedly secured substantially at the center thereof. The thickness of the thermocouple is preferably sufficient to protrude very slightly from the flat dielectric anterior surface. Thermocouple output wires 210, connected to thermocouple 208, extend through the length of groove 206 to the outside of waveguide 200, as shown in FIGURE 2. Thermocouple output wires 210 constitute feedback connection 106 of FIGURE 1.

The therapeutic purpose of applicator 102 in the treatment of glaucoma is to apply sufficient microwave energy to the ciliary body to effect cyclodestruction without creating collateral eye damage. This is accomplished by first positioning 0.03 square inch dielectric radiating aperture 204 in contact with the anterior surface of applicator 102 in contact with a 0.03 square inch spot on the outer surface of the sclera which overlies the ciliary body

(e.g., a spot displaced about 2 millimeters beyond the outer edge of the iris). This inherently places thermocouple 208 in contact with this spot. The applicator is energized with microwave energy having a frequency (e.g. 5,000 to 6,000 MHz) which readily
5 penetrates the thickness of the scleral tissue with little absorption and reaches a corresponding spot of the underlying ciliary body, where it is readily absorbed. The reason for this is shown by the FIGURE 3 chart, which will be discussed below.

The microwave energy is applied to the spot for a given
10 time (e.g., one minute) which is a sufficient time for the irradiated spot of the ciliary body to be heated to a high enough temperature to cause cyclodestruction, while the sclera itself is never heated enough to raise its temperature sufficiently high to result in damage thereto. (The FIGURE 4 chart, discussed in more detail
15 below, indicates the the relationship between temperature and time of heating duration that results in damage to different types of mammalian tissue.) In any event, the thermostatic control of microwave generator 100 is set so that the radiated microwave energy is cut off whenever the temperature of thermocouple 208
20 rises to a preselected therapeutic temperature which is below the temperature at which scleral damage occurs. Thus, the continuous monitoring of sclera-spot surface temperature by thermocouple 208 maintains the temperature substantially constant at the therapeutic temperature and also ensures that the operation is
25 fail-safe.

In order to complete the microwave cyclodestruction procedure, the above-described process is applied sequentially to each of several (e.g., five) displaced spots on the outer surface of the sclera. More specifically, after the above-described process
30 with respect to one of the several displaced spots is completed, the applicator is displaced by about the width of applicator 102 (200 mils) to another similar scleral spot overlying the ciliary body. Thus, the resulting several displaced spots tend to lie on the circumference of a circle having a radius about 2 millimeters
35 larger than that of the iris.

Referring to the FIGURE 3 chart, there is shown the penetration depth as a function of frequency at which $1/e$ (where

e is the base of natural logarithm) of incident microwave energy is absorbed by low-water-content human tissue and by high-water-content human tissue, respectively. It is apparent from this chart that low-water-content human tissue is much more microwave
5 absorbent than high-water-content human tissue. Scleral human tissue is low-water-content human tissue and ciliary-body tissue is high-water-content human tissue. Thus, most of the applied microwave energy merely passes through the thickness of the scleral tissue to be then highly absorbed by the underlying
10 ciliary-body tissue, thereby preferentially heating the underlying ciliary-body tissue.

Referring to the FIGURE 4 chart, there is shown temperature- time duration thresholds for damage to occur in different types of mammalian tissue. As indicated by the wide
15 band of the FIGURE 4 chart, for a given heating duration some types of tissue (e.g., corneal tissue) are damaged substantially less than others. It has been found that both corneal and scleral tissue are not damaged by, and tolerate well, being heated to a temperature up to about 50° C for at least one minute. Therefore,
20 the aforesaid fail-safe thermostatically-controlled therapeutic temperature for a heating duration of scleral tissue for one minute certainly may be set at 50° C, and perhaps even somewhat higher.

Returning to FIGURE 2, the high dielectric constant of the dielectric filling of waveguide 200 of applicator 102 serves two
25 important purposes. First, by reducing the microwave wavelength traveling therein for a given microwave frequency, the size of applicator 102 for transporting that given microwave frequency may be reduced (i.e., miniaturized). Second, the high dielectric constant of the dielectric filling of waveguide 200 more nearly
30 matches the high dielectric constant of the high-water content ciliary body, and, therefore, enhances microwave power transfer from dielectric radiating aperture 204 to the ciliary body. Further, for microwave power transfer purposes, the impedance at the microwave input to applicator 102 at the posterior end of
35 waveguide 200 should closely match that presented by transmission line 104, and the impedance at the microwave output from applicator 102 at dielectric radiating aperture 204

(located at the anterior end of waveguide 200) should closely match that presented by the scleral tissue with which it is in contact. The proper impedance matching at both the posterior and anterior ends of waveguide 200 is achieved by the above-
5 discussed tapering of the thickness of waveguide 200 from 100 mils at its posterior end to 150 mils at its anterior end.

The above-described controlled microwave cyclodestruction procedure has been tested experimentally in the treatment of induced glaucoma in the eyes of rabbits. Microwave induced
10 cyclodestruction was successful in reducing the intraocular pressure in all treated glaucomatous eyes for a 4 week duration. Two additional glaucomatous eyes were left untreated, served as controls, and were noted to have persistently elevated intraocular pressures. Then 6 additional eyes were subjected to an equivalent
15 treatment (50°C x 1 min. x 5 applications) which resulted in approximately 180° of heat treatment just posterior to the corneal-scleral limbus. These specimens were evaluated by light microscopy at time 0, 24 hours, and at 7 days after treatment.

Clinical and histopathologic evaluations suggested that
20 microwave thermotherapy (delivered under thermometry control) allowed for chorioretinal/ciliary body destruction which resulted in reductions of intraocular pressure in glaucomatous eyes.

WHAT IS CLAIMED IS:

1. A method for treating glaucoma by cyclodestruction; said method comprising the steps of:
 - (a) supplying microwave energy to ciliary-body tissue through a given spot on the outer surface of scleral tissue which
5 overlies said ciliary-body tissue;
 - (b) continuously monitoring the temperature of said given spot; and
 - (c) thermostatically controlling the supply of said microwave energy in accordance with said continuously-monitored
10 temperature to maintain the temperature of said given spot substantially constant at a preselected value which is below that which would result in damage to said scleral tissue, while permitting the temperature of said ciliary body itself to be raised to a given temperature for a given time by said microwave energy
15 supplied thereto, said given temperature and said given time being sufficient to effect cyclodestruction of said ciliary-body tissue.
2. The method defined in Claim 1, wherein step (a) comprises the step of:
 - (d) supplying microwave energy to said given spot having a frequency value which readily penetrates the thickness of said
5 scleral tissue with little absorption and reaches a corresponding spot of said underlying ciliary body tissue, where it is readily absorbed.
3. The method defined in Claim 2, wherein said frequency value is in a range of 5,000 to 6,000 MHz.
4. The method defined in Claim 1, wherein said preselected value of said temperature of said given spot is no greater than 50°C.
5. The method defined in Claim 4, wherein said given time is of the order of one minute.

6. The method defined in Claim 1, wherein step (a) comprises the step of:

(d) supplying microwave energy to a substantially 0.03 square inch given spot situated on the outer surface of scleral tissue substantially 2 millimeters beyond the outer edge of an eye's iris.

7. The method defined in Claim 1, wherein step (a) comprises the step of:

(d) supplying microwave energy in sequence to ciliary-body tissue through each of a plurality of separate given spots on the outer surface of scleral tissue all of which overly said ciliary-body tissue.

8. The method defined in Claim 7, wherein step (d) comprises the step of:

(d) supplying microwave energy to each of a plurality of displaced, substantially 0.03 square-inch, given spots situated on the outer surface of scleral tissue substantially 2 millimeters beyond the outer edge of an eye's iris, the displacement between adjacent given spots being substantially 200 mils.

9. A microwave applicator useful in the treatment of glaucoma by cyclodestruction; said applicator comprising a waveguide responsive to a microwave input of a given frequency supplied thereto at its posterior end for radiating microwave energy of said given frequency from the surface of an aperture situated at its anterior end; wherein:

said waveguide includes a thin metal wall filled with solid dielectric material having a given dielectric constant that extends between said anterior and posterior ends and has a given area at said radiating aperture, whereby said radiating aperture is a dielectric radiating aperture;

said surface of said dielectric radiating aperture has a groove therein for housing a thermocouple;

15 said given dielectric constant of said solid dielectric material
has a value in the vicinity of that of water; and

the size of said given area is sufficiently small to permit said
dielectric radiating aperture to contact only a given spot of scleral
tissue of an eye that overlies substantially solely ciliary-body
tissue of said eye.

20

10. The method defined in Claim 9, wherein:

said solid dielectric material consists of a ceramic block
having said given dielectric constant.

11. The method defined in Claim 10, wherein:

said given dielectric constant has a value of substantially 85.

12. The method defined in Claim 10, wherein:

said thin metal wall comprises a metal plating on the surface
of said ceramic block.

13. The method defined in Claim 9, wherein:

the size of said given area is substantially 0.03 square inch.

14. The method defined in Claim 9, wherein said microwave
input is supplied to said posterior end of said waveguide by
transmission means exhibiting a predetermined characteristic
impedance; and wherein:

5 said thin metal wall filled with solid dielectric material has a
second given area of a certain size at the posterior end of said
waveguide, said certain size being such as to provide said
waveguide with an input impedance that substantially matches
said predetermined characteristic impedance exhibited by said
10 transmission means.

15. The method defined in Claim 14, wherein:

the size of said second given area is different from that of
said first-mentioned given area, and the cross section area of said
thin metal wall filled with solid dielectric material tapers in size
5 between said second and first-mentioned given areas.

16. The method defined in Claim 15, wherein:
said first-mentioned given area has a width of substantially
200 mil and a thickness of substantially 150 mil; and
said second given area has a width of substantially 200 mil
5 and a thickness of substantially 100 mil.

17. The method defined in Claim 9, further comprising:
a thermocouple situated within said surface groove in said
dielectric radiating aperture; and
thermocouple output wires adapted to deliver a signal
5 indicative of the temperature of said thermocouple to external
means for thermostatically controlling said microwave input
supplied at said posterior end of said waveguide in order to
prevent said thermocouple temperature from ever exceeding a
temperature having a preselected value that is below that which
10 would result in damage to scleral tissue
whereby microwave energy radiated from said dielectric
aperture of said applicator may be used to to effect
cyclodestruction by positioning said dielectric aperture in contact
with said given spot on the outer surface of scleral tissue which
15 overlies ciliary-body tissue, thereby also situating said
thermocouple in contact with said given spot.

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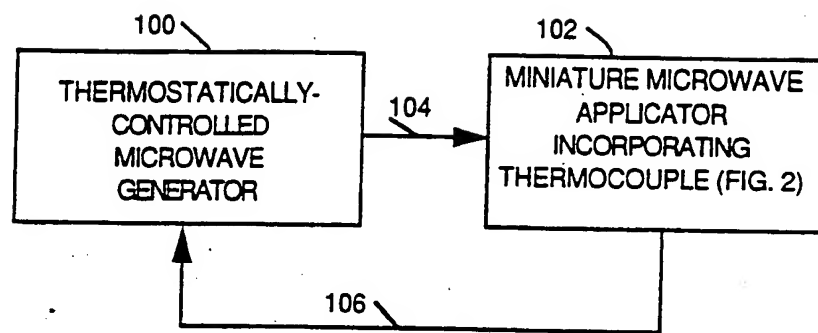


FIGURE 1

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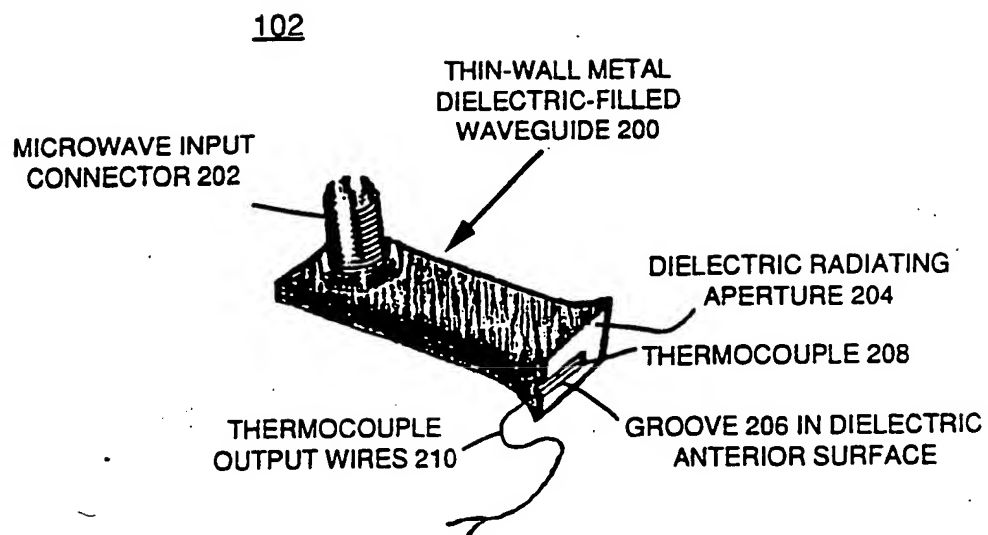
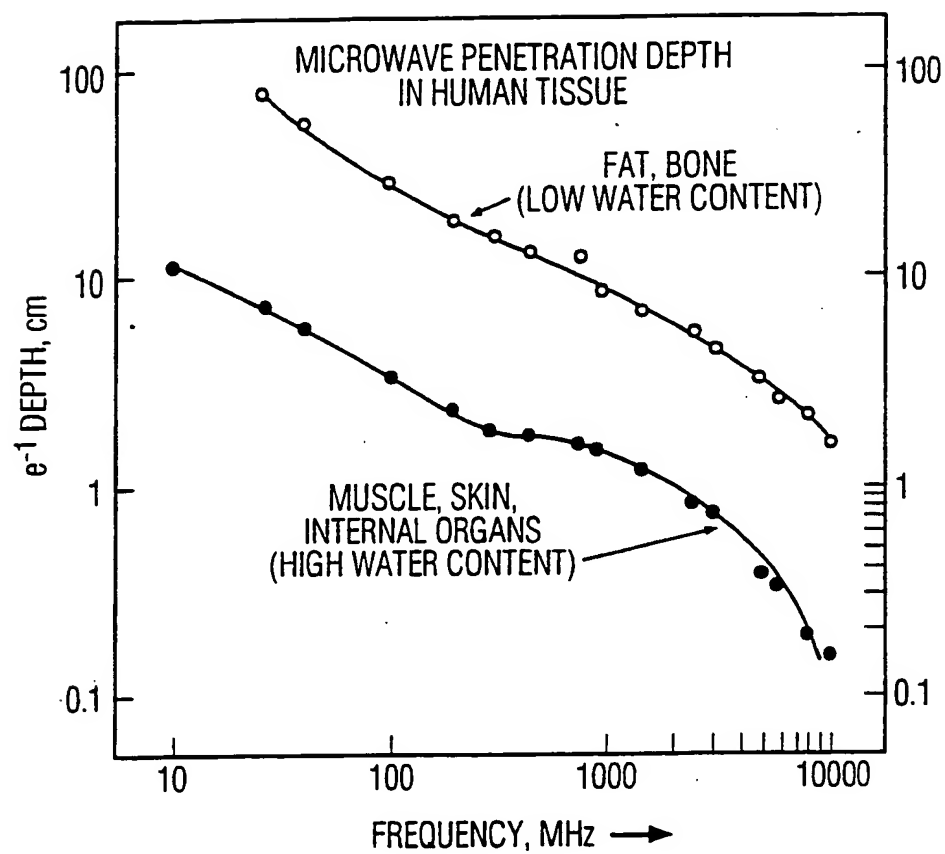


FIGURE 2

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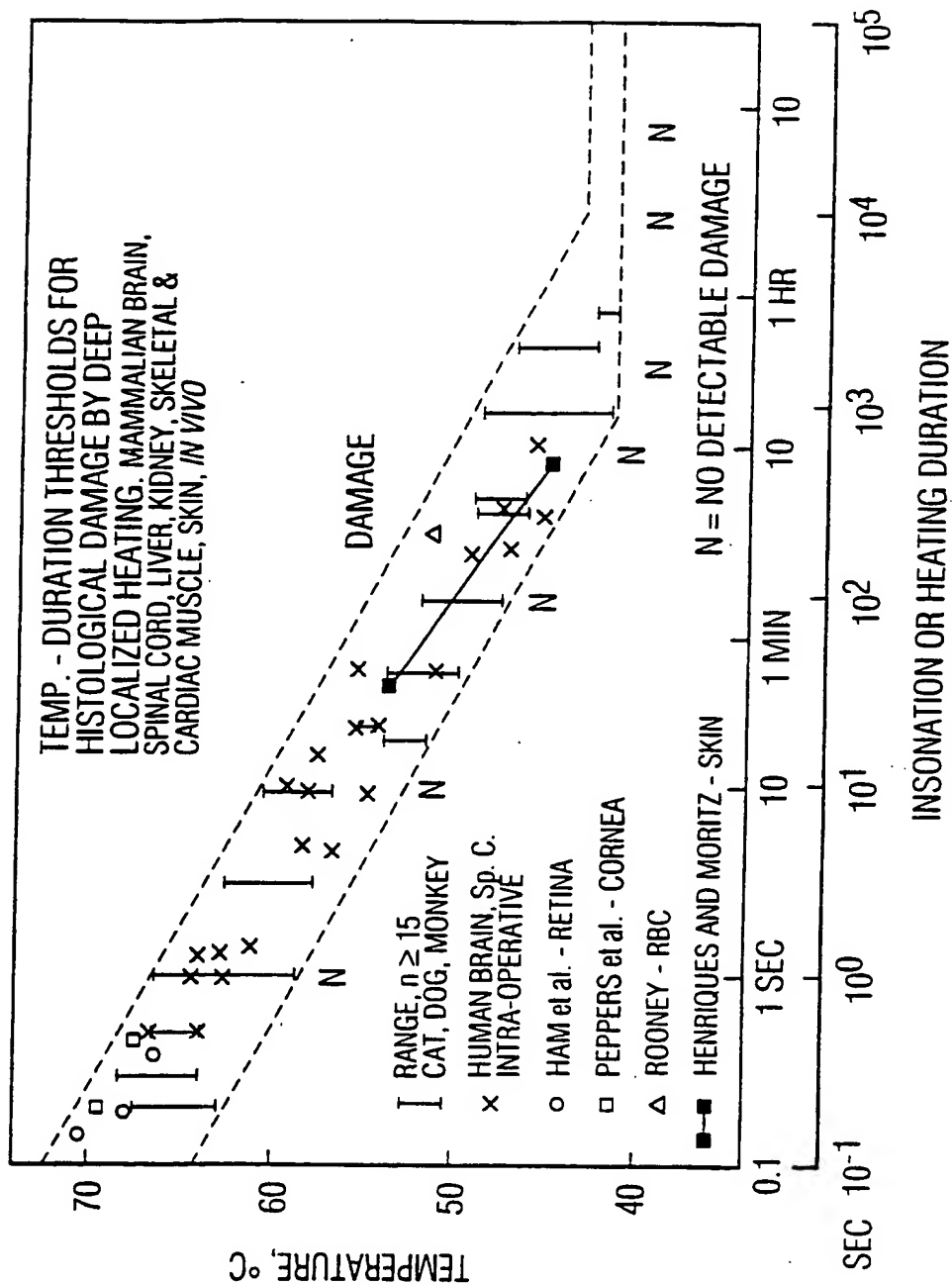
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**FIGURE 3**

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FIGURE 4



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INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US92/03425**

I. CLASSIFICATION OF SUBJECT MATTER

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): **B23K 15/10**
 US Cl.: **219/10.55B ; 128/804**

II. FIELDS SEARCHED

Minimum Documentation Searched *

Classification System

Classification Symbols

US **219/10.55A, 10.55B, 10.55F, 10.55M ; 73/359R, 355EM**
128/399, 413, 736, 784, 788, 800, 804 ; 604/20; 606/3,4,11

Documentation Searched other than Minimum Documentation
 to the Extent that such Documents are Included in the Fields Searched *

III. DOCUMENTS CONSIDERED TO BE RELEVANT *

| Category * | Citation of Document, ** with indication, where appropriate, of the relevant passages ** | Relevant to Claim No. ** |
|----------------------|--|--|
| <u>X</u> <u>Y</u> | US,A, 4,204,549 (Paglione) 27 May 1980 (See the entire document) | 1-2,7,9-10,12, 14-15,17 3-6,8,11,13,16 |
| A | US,A, 4,589,424 (Vaguine) 20 May 1986 (See entire document) | 1-17 |
| A | US,A, 4,190,053 (Sterzer) 26 February 1980 (See the entire document) | 1-17 |
| A | US,A, 4,271,848 (Turner et al) 09 June 1981 (See the entire document) | 1-17 |
| A | US,A, 4,282,887 (Sterzer) 11 August 1981 (See the entire document) | 1-17 |
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IV. CERTIFICATION

Date of the Actual Completion of the International Search

26 June 1992

Date of Mailing of this International Search Report

21 JUL 1992

International Searching Authority

ISA/US

Signature of Authorized Officer

Tu Hoang
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NGUYEN NGOC-HO

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